DEC 2 3 2003

510(k) Summary

Date: Nov 12, 2003

Assigned 510(k) "K" Number K033695

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

1. Company making the submission:

	Company
Name: Address: Telephone: Fax: Contact:	Byrne Medical, Inc. 2021 Airport Road Conroe, TX 77304 800-490-9869 936-588-0392 Don Byrne President Don@byrnemedical.com

2. Device:

Proprietary Name:	Irrigation Channel Tubing System
Common Name:	Endoscope and accessories
Classification Name:	Accessories, Cleaning, for Endoscope

3. Predicate Devices:

Device Name	Manufacturer	"K" #
Endo Gator™ System	Byrne Medical	K031773
Lsi Endoscope External Accessory	Lsi Solutions	K024301

4. Classification and Product Code: 21 CFR § 876.1500, Class II, 78 KOG.

5. Description:

100135 – Byrne Medical Irrigation Channel Tubing provides extension tubing to the EndoGator™ System to an Endoscope. The EndoGator™ System is utilized to provide fluid (water) to clean the Endoscope lens area.
The Endo Gator™ System tubing sets are sold as a sterile, single patient use device. It is packaged in a Chevron-style sterile barrier pouch with product label affixed to the clear side of the package.

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6. Indications for Use Statement:

The Byrne Medical Irrigation Channel Tubing is used with the Byrne Medical Endo Gator™ System and connects to the output tubing from the pump and goes down the channel of an Endoscope. The Byrne Medical Irrigation Channel Tubing is provided sterile and is labeled for single use only.

6. Summary of Technological Characteristics and Differences:

The Endo Gator™ Irrigation Channel Tubing system does not allow passage of additional endoscopic instruments, as does the Lsi Solutions device.

The Endo Gator System and the Irrigation Channel Tubing system and all predicate devices provide water to irrigator pumps or cauterizing units.

7. Contraindications:

The Endo Gator™ System is not designed, sold or intended for use except as indicated.

No other contraindications are known for this device.

8. Comparison:

The Byrne Medical Irrigation Channel Tubing System has the same device characteristics and the predicate devices. Difference between some systems is providing tubing sets sterile for single patient use. The Byrne Medical Irrigation Channel Tubing System allows only the passage of water from the pump.

9. Test Data:

The Byrne Medical Endo Gator™ Irrigation Channel Tubing system has been subjected to extensive safety, performance, and validations prior to release.

Bench testing was conducted utilizing Meditron UGI-3000B™GI Endoscopy Therapy System and Endolav® Endoscopic Lavage Pumps and EndoGator™ Cartridge and tubing sets.

Flow testing was completed at the minimum and maximum settings of the pump systems. Water flow was measured as a function of total volume over time. In each test the minimum pump setting produced 155 ml/min and maximum produced 650 ml/min with a measurement error of +/- 4%.

Pressure testing – EndoGator™ Irrigation Channel Tubing system was tested to 10 PSI without leaking or any other failure. The pump manufacturer's stated maximum pressure is 4.4 PSI.

10. Conclusions:

The conclusion drawn from these tests is that the Byrne Medical Endo Gator™ Irrigation Channel Tubing System is equivalent in safety and efficacy to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2003

Byrne Medical, Inc.
c/o N. E. Devine, Jr.
Entela, Inc.
3033 Madison Ave. SE
GRAND RAPIDS MI 49548

Re: K033695
Trade/Device Name: Irrigation Channel Tubing System, Model 100135
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 KOG
Dated: December 9, 2003
Received: December 11, 2003

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number K 033695

Device Name: Irrigation Channel Tubing System.

Indications for use:

The Byrne Medical Irrigation Channel Tubing is used with the Byrne Medical Endo Gator System and connects to the output tubing from the pump and goes down the channel of an Endoscope. The Byrne Medical Irrigation Channel Tubing is provided sterile and is labeled for single use only.

Prescription Device:

Federal Law (US) restricts this device to sale by or on the order of a physician.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K033695

(Optional Format 1-2-96)